DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
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September 18, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-100

Douglas A. Drum, President
Indian Valley Meats, Inc.
52 Huot Circle
Indian, Alaska 99540

WARNING LETTER

Dear Mr. Drum:

We inspected your firm located at 52 Huot Circle, Indian, Alaska, on November 10, 15, and 16, 1999, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your hot smoked fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(c)(1). Your firm's HACCP plan for Hot Smoked Commercial Fisheries Products does not list the food safety hazard of pathogen growth and toxin formation. This deviation was previously brought to your attention in our letter of April 12, 1999.

   Spore forming pathogens, such as *Bacillus cereus* could survive your cook, germinate, and produce toxins if the product is inadequately cooled. While your HACCP plan for Hot Smoked Commercial Fisheries Products includes a reference to cooling parameters (CCP.5), it does not identify the hazard, i.e., pathogens, for the steps related to cooling.

   Further, once the product has had human contact or opportunity for cross-contamination after cooking, there is a potential for additional pathogen growth under conditions of time and temperature abuse. Your HACCP plan for Hot Smoked Commercial Fisheries Products does not identify this hazard, i.e., pathogens, for the steps related to packing and labeling (CCP.5). Note that if the properly chilled product is packaged and labeled rapidly and then placed back into the cooler, the pathogen

hazard may not need to be addressed at the packaging or labeling steps but should be considered in your hazard analysis of cumulative time/temperature abuse. Appropriate critical limits, monitoring procedures, verification procedures, and record keeping should also be listed in your HACCP plan at the critical control points identified to control the pathogen hazard.

2. You must have a HACCP plan that lists monitoring procedures for each critical control point, in order to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for Hot Smoked Commercial Fisheries Products:

   a) lists a monitoring procedure at the brining critical control point (CCP.2) that is not adequate to control the hazard of *Clostridium botulinum* toxin formation. It is not clear from your plan how the brining ingredients are to be measured or who will perform the monitoring during the brining steps, including monitoring of temperature controls;

   b) lists the monitoring procedures at the drying/smoking/cooking/cooling and final product storage critical control points (CCP.5) that are not adequate to control the hazard of *Clostridium botulinum* toxin formation or other pathogens;

      i) It is not clear from your plan who will perform the monitoring during the drying/smoking/cooking steps.
      ii) It is not clear from your plan how the internal product temperature are determined during cooling or who will perform the monitoring.
      iii) Your plan identifies a thermometer for measuring final product storage cooler temperatures. However, it is not clear how often, or by whom the monitoring of this critical control point is to occur.

3. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, your firm maintained sanitation control records that are not adequate. The records do not address prevention of cross contamination; protection from chemical, physical, and biological hazards; proper labeling, storage, and use of toxic compounds; control of employee health; and exclusion of pests.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. Pertinent sections of the Act and regulations are enclosed for your review.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

Bruce W. Williamson

for Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
ADEC